

Examiner is respectfully directed to the fact that amended claims 1 and 117 comprise limitations related to folic acid that are similar to limitations related to folic acid in independent claims 37 and 134. Therefore, for the same reasons that claims 37 and 134 are distinguishable over Riley, claims 1 and 117 are novel as well. Accordingly, Applicants respectfully request reconsideration and withdrawal of the pending rejections under 35 U.S.C. § 102.

Referring again to the Advisory Action, the Examiner alleges that the Reply and Amendment Pursuant to 37 C.F.R. § 1.116 filed on 13 November 2002 does not place the application in condition for allowance. Paper No. 10 at page 2. Specifically, the Examiner maintains that the pending claims are obvious in light of Riley. *Id.* Applicants respectfully traverse.

When relying upon a reference in support of an obviousness determination, the Examiner must specifically identify how or why one of ordinary skill in the art would have been motivated to make a claimed invention in view of the reference. In other words, the *prima facie* burden is upon an Examiner to explain the reasons one of ordinary skill in the art would have been motivated to select a reference and how one would have utilized the reference to render a claimed invention obvious. *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002). The need for specificity pervades Federal Circuit authority related to determinations of obviousness. *Id.* Further, although a suggestion to rely upon a reference in the context of an obviousness determination may come from the nature of a problem to be solved, there must be some relationship between a claim limitation and the problem itself. *Pro-Mold & Tool Co. v. Great Lakes Plastics*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

There is no such relationship here. The Examiner has not satisfactorily set forth how or why one of ordinary skill in the art, in view of Riley, would have been motivated to make the compositions with the recited ranges of elements claimed in the present application. Indeed, the Examiner's assertions seem to be mere conclusory statements that "employment of known salts of known actives" and the "optimization of amounts (e.g., amount of folate or other components)" are within the purview of the skilled artisan and therefore obvious. Paper No. 10 at page 2. The Examiner has not met the burden of establishing why one of ordinary skill in the art would have been motivated to specifically manipulate the compositions of Riley to achieve the claimed compositions. Absent a showing of such a specific motivation, the Examiner has impermissibly applied an "obvious to try" standard, which suffers from a hindsight application that the Federal Circuit has rejected. *In re O'Farrell*, 853 F.2d 894, 903

(Fed. Cir. 1988); *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995) ("Obvious to try" has long been held not to constitute obviousness.").

Accordingly, Applicants respectfully request reconsideration and withdrawal of the pending rejections under 35 U.S.C. § 103.


### CONCLUSION

Applicants respectfully request that the Examiner enter the amendments proposed within the Reply and Amendment Pursuant to 37 C.F.R. § 1.116 filed on 13 November 2002, consider the present remarks, and reconsider and withdraw all pending rejections. Should there be any further matters requiring consideration, the Examiner is invited to contact the undersigned counsel.

If there are any further fees due in connection with the filing of the present reply, please charge the fees to undersigned's Deposit Account No. 50-1067. If a fee is required for an extension of time not accounted for, such an extension is requested and the fee should also be charged to undersigned's deposit account.

Respectfully submitted,

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